Full title: Developing an Intervention for Falls in Dementia: Work Package 4

Short title/Acronym: DIFRID WP4

Protocol version number: 2.0

Date: 12th October 2017

Statement: This protocol has regard for the HRA guidance.

RESEARCH REFERENCE NUMBERS

IRAS Number: **227451**

NHS REC Reference:

ISRCTN Reference: **41760734**

NIHR Portfolio Reference:

RESEARCH SPONSOR

Sponsor Name: The Newcastle upon Tyne Hospitals NHS Foundation Trust

Sponsor Reference: 8489

RESEARCH FUNDER

Funder Name: NIHR Health Technology Assessment Programme

Funder Reference: 13/78/02

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I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor.

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TRIAL SUMMARY

Trial Title	Developing an Intervention for Fall Related Injuries in Dementia: Work Package 4
Acronym	DIFRID WP4
Summary of Trial Design	Feasibility study with embedded qualitative study Health technology assessed: Feasibility of study procedures, suitability and acceptability of outcome measures, acceptability, feasibility and fidelity of intervention components. Final output: Description of a complex intervention with accompanying training materials for its delivery and measurement of outcomes
Summary of Participant Population	PWD presenting with falls needing healthcare attention in each setting at each site and their informal carers. Professionals delivering the intervention, responsible for training and supervision and members of the intervention MDT. Professionals working into study sites who have contact with the intervention team. Professionals responsible for approaching and recruiting participants.
Planned Sample Size	A total of up to 88 participants. 10 patient and informal carer dyads in each of 3 sites for the intervention (some of whom will also participate in the embedded qualitative study). 28 professionals for the embedded qualitative study.
Planned Number of Sites	3 UK sites (Newcastle, Stockton and Tees, Norfolk) each including the following services: 1. Community services (Primary care, Paramedics, Telecare) 2. Secondary care (ED; Facilitated Discharge Services; Rehabilitation Outreach Teams) 3. Case and research registers
Intervention duration	12 weeks.
Follow Up Duration	12 weeks (to coincide with the end of the intervention)
Planned Trial Period	5 months.
Primary Objective	To investigate the feasibility and acceptability of the DIFRID intervention and the feasibility of a future randomised controlled trial (RCT) to evaluate the efficacy of the DIFRID intervention.

Intervention	The intervention will be a complex multidisciplinary intervention taking place mainly in the patient's home over a period of 12 weeks.
Outcome Measures	Assessment of feasibility of study procedures Assessment of suitability and acceptability of outcome measures Assessment of the acceptability, feasibility and fidelity of intervention components

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GLOSSARY OF ABBREVIATIONS

ABBREVIATION	DEFINITION
ADLs	Activities of Daily Living
QOL-AD	Quality of Life in Alzheimer's Disease
AE	Adverse Event
CCG	Clinical Commissioning Group
CI	Chief Investigator
CMOcs	Context-Mechanism-Outcome configurations
CRF	Case Report Form
CRN	Clinical Research Network
CTA	Clinical Trials Associate
DAD	Disability Assessment for Dementia
ED	Emergency Department
EQ-5D-5L	European Quality of Life Instrument
GAS	Goal Attainment Scaling
GCP	Good Clinical Practice
GP	General Practitioner
HRA	Health Research Authority
HUQ	Health Utilisation Questionnaire
ICD	International Classification of diseases
ISF	Investigator Site File
JDR	Join Dementia Research
MDT	Multidisciplinary Team
MFES	Modified Falls Efficacy Scale
NGT-R	Nominal Group Technique – RAND Corporation
NHS	National Health Service

NPT	Normalisation Process Theory
PI	Principal Investigator
PIS	Participant Information Sheet
PMG	Programme Management Group
PPI	Patient and Public Involvement
PWD	Person or people with dementia
QOF	Quality Outcomes Framework
R&D	Research and Development
RCT	Randomised Controlled Trial
REC	NHS Research Ethics Committee
SOP	Standard Operating Procedure
SRA	Senior Research Associate
TMF	Trial Master File
TOC	Trial Oversight Committee
WP	Work package
ZBI	Zarit Burden Interview

1 BACKGROUND

It is estimated that, in 2011, 670,000 people were living with dementia in the UK, 70% of whom live in their own homes and often receive extensive support from informal carers[1]. Although the prevalence of dementia is decreasing among older people, the ageing population means that the absolute numbers of people with dementia (PWD) will continue to rise. In our previous study the annual prevalence of falls in PWD ranged from 47-90%, depending on dementia subtype, and PWD living in their own home sustained almost 10 times more incident falls than controls, and their falls were more likely to be injurious[2]. PWD are less likely to recover well after a fall, more likely to be hospitalised, are hospitalised for longer and are more likely to require increased care[3]. Falls and fall related injuries are therefore a significant cause of morbidity and mortality in PWD. There is presently little evidence to guide the management of such falls and injuries, and yet there are potentially substantial benefits to be gained if the outcome of these falls and injuries could be improved. The DIFRID study aims to provide the evidence needed for the design of an appropriate healthcare intervention for such PWD and to assess the feasibility of its delivery in the clinical setting. The original brief for this trial from the NIHR Health Technology Assessment Programme asked us to focus on PWD who had sustained a fall related injury. As a result of work undertaken so far, our brief has now changed to include all PWD who have sustained a fall, either with or without an injury, requiring healthcare attention. So far, three work packages (WPs) have been undertaken and this protocol applies to WP 4. WPs 1-3 are described below to provide context for WP4.

1.1 Work Package 1: Literature reviews

WP1 examined the literature regarding interventions for PWD after a fall. The strategy for reviewing literature included review of bibliographic sources, existing investigator reference databases, grey literature and key references as identified from experts in the field to identify studies examining: the health and social care needs of PWD with fall related injuries, outcomes of importance to patients/informal carers and evidence on the relative effectiveness of interventions.

Using Cochrane methodology, we found that, due to high heterogeneity across the studies, definitive conclusions could not be reached. Most post-fall interventions aimed at PWD have shown little efficacy. Minor improvements to some quality of life indicators were shown, but these were generally not statistically significant.

Given the paucity of the literature found using Cochrane methodology, we also conducted a realist review[4]. Following stakeholder engagement work in WP2.1 (see below) we developed a set of Context-Mechanism-Outcome configurations (CMOcs) which theorise how the composition of an intervention may help to address the specific challenges of rehabilitation with PWD following a fall. We then refined the CMOcs using evidence from further literature searches.

The CMOcs cover three broad areas:

- Ensuring that the circumstances of rehabilitation are optimised for PWD
- Compensating for the reduced ability of PWD to self-manage
- Equipping the workforce with the necessary skills and information to care for this patient group

Based on this synthesis, we compiled some suggested intervention components, including:

- Design rehabilitation strategies around repetition and embedding
- Ensure that multiple sources are used when gathering information
- Provide training for staff
- Ensure that basic needs such as appropriate food, water, comfort and pain relief are met
- Implement strategies to aid with carer burden and stress
- Implement a structured holistic assessment
- Deliver intervention through multidisciplinary teams (MDTs)

1.2 Work Package 2: Understanding current practice and describing current usual care

WP2 comprised three elements, each conducted in three UK sites: Newcastle, Stockton and Tees, and Norfolk.

WP2.1 explored health and social care professionals' views of existing services and the perceived value, content and delivery of a new intervention. Qualitative interviews and focus groups with staff working in existing services for this patient group were undertaken. Data were collected on current care pathways; ideas for an intervention; factors thought to help or hinder the delivery of interventions for fall-related injuries in dementia; and outcome measures used by existing services. Interviews and focus groups were recorded and analysed thematically. The data from this study was used to inform the CMOcs for our realist review as described above.

WP2.2 explored current service provision for PWD who fall. Participants included PWD, informal carers, and professionals working in services identified during WP2.1. Data were collected through observation of routine practice and interviews. Integrative thematic analysis of this data together with qualitative data from WP2.1 and 2.3 suggested that improving outcomes for PWD with fall-related injuries requires recognition and facilitation of rehabilitation potential. This in turn requires services and staff to work in ways that compensate for cognitive impairment. We identified four factors which influence the extent to which current services achieve these aims:

- Supportive service organisation
- Staff attitudes, knowledge and skills
- Maximising the engagement of PWD
- Supporting informal carers and their role in interventions

WP2.3 was a prospective observational study over 6 months. It included three settings within each of our three sites: primary care consultations, paramedic attendances, and emergency departments (ED). The target population was PWD presenting with fall related injuries. We assessed the procedure for ascertaining that potential participants had a diagnosis of dementia, estimated the number of PWD presenting in each setting, and identified service use after the fall. We found that 266 PWD presented via the three sites in a six-month period. Thirteen PWD and their informal carers kept a diary of service usage for three months to describe the care pathways followed. Further qualitative interviews explored PWD and carer perceptions of their care needs, whether these needs were met, what could have been improved, and what outcomes were important to them.

1.3 Work Package 3: Intervention development and validation

In WP3, we convened two meetings of an expert consensus panel to help us design the intervention. The panel was asked to review the results of WPs 1 and 2, assess the feasibility and appropriate setting for recruiting participants to receive the intervention, assess and prioritise specific elements to be combined in a complex health care intervention, identify the most appropriate setting for delivery of the intervention, identify professionals required and their training needs, and identify and prioritise outcomes to be measured.

The recommendations of the panel regarding the design of the intervention were assimilated using methods of the RAND Nominal Group Technique (NGT-R, also known as the modified Delphi panel approach)[5]. NGT-R uses structured interaction within a group and is commonly applied when decisions and care needs are complex and the evidence base is limited. This approach ensured the design of the new intervention took account of the full range of stakeholders' views and not just the views of the research team. Between the two panel meetings, online surveys were used to achieve consensus on: the design and setting of the intervention; the content of the manualised procedures for delivery; and outcome measurement. The consensus statements are given in Appendix 1.

A significant change to the population of the study was recommended following review of data from WPs 2 and 3, namely that PWD who had fallen but not sustained a physical injury should be included. On the advice of the Trial Oversight Committee (TOC) this was refined to those with a fall, with or without an injury, but requiring healthcare attention.

Further qualitative interviews and focus groups were undertaken to explore the acceptability of the proposed intervention with a range of stakeholders, including those identified in WP2. The results were presented to the expert panel at their second meeting. The research team developed manuals for the intervention based on the findings of the Delphi panel and the manualised intervention for WP4 was finalised after feedback from the panel.

1.4 Work Package 4: Feasibility study of the DIFRID intervention

This protocol now describes WP4, which aims to assess the feasibility and acceptability of the intervention and selected study procedures, and identify any changes needed prior to a full scale clinical trial.

Using mixed methods, we will assess the acceptability and feasibility of participant recruitment, outcome measurement, and intervention delivery.

The final output of the study will be a description of a validated complex intervention with accompanying training materials for its delivery and measurement of outcomes. If found to be feasible, future work will be a full-scale randomised controlled trial (RCT) to improve outcomes for PWD who have had a fall requiring healthcare attention.

2 RATIONALE

PWD who sustain falls currently receive a range of health interventions, but a single model of care for this specific situation has not previously been described and the feasibility of such an intervention is not known. Given the frequency of this problem in PWD it is clear that this is an important area for research. There is also no current consensus on the best outcomes to measure the impact of such an intervention or its cost effectiveness and therefore research is required to identify suitable outcome measures.

3 OBJECTIVES AND OUTCOME MEASURES

The overall aim of this study is to assess whether it is possible to design a complex intervention to improve the outcome of falls requiring healthcare attention in PWD living in their own homes. In WP4 we are testing a new complex intervention.

3.1 Primary Objectives

To conduct a single arm feasibility study, to deliver the proposed intervention to 10 patient-informal carer dyads in each of the 3 sites.

3.2 Secondary Objective(s)

To assess the factors influencing the acceptability and implementation of the intervention and to determine whether to progress to a full-scale RCT.

3.3 Outcomes

As this is a feasibility study, we will consider a range of outcomes relating to the delivery of the intervention, the feasibility and acceptability of recruitment; and the outcome measures.

3.3.1 Assessment of the feasibility and acceptability of intervention delivery

Since the intervention is multi-dimensional and tailored to the individual we will use mixed methods and seek the views of a range of stakeholders. Quantitative analysis will consider:

- The proportion of staff attending all training and supervision sessions and multidisciplinary team (MDT) meetings
- The number, frequency and duration of training and supervision sessions, and MDT meetings
- Time spent with the patient and time spent travelling to appointments
- The proportion of patients discussed at MDT meetings and actions taken
- The proportion of patients seen by a geriatrician
- The proportion of patients reviewed by the MDT at six and twelve weeks and actions taken
- How the assessment documentation was used in practice, for example, whether all sections were completed
- The nature of goals set and alignment of activities with these goals
- Referrals made to other services
- Adherence with agreed activities by PWD.

Much of these data will be gathered through documentary review and structured proformas to be maintained by staff responsible for either supervising or delivering the intervention. Data on each intervention visit will be recorded allowing us to analyse the number of visits, time taken and interventions delivered and to estimate intervention costs. Adherence of PWD to activities will be captured in the project diary.

Additional qualitative work will provide a more nuanced understanding of these data and allow us to explore whether and how the intervention will need to be adapted prior to a full trial. We will either directly observe or use audio recordings of intervention training, delivery and supervision in all sites; this will enable us to explore adherence and variation between and within sites. Observation will be supplemented with semi-structured interviews with a range of stakeholders to explore:

- The 'fit' of the intervention with staff usual working practices
- The acceptability of the intervention and suggested changes or improvements to the content, delivery or timing of the intervention
- Assessment of training and intervention delivery
- The feasibility and perceived value of MDT meetings
- The feasibility of different components of the intervention (e.g. goal setting and tailoring)

To ensure that we capture the views of different stakeholders we will interview staff delivering training and supervision; staff delivering the intervention; members of the MDT; PWD and informal carers receiving the intervention; and health and social care staff who are concurrently providing care to the PWD and/or to whom the PWD is referred during the intervention.

In a previous process evaluation [15], we found informal discussions to be a very effective way of collecting data in a timely fashion. Such discussions may only last a few minutes but can deepen understanding of how the intervention is being delivered. We anticipate that informal discussions will be conducted throughout the WP4 with staff responsible for training and supervision and those responsible for intervention delivery.

3.3.2 Feasibility of recruitment and retention

We will explore the feasibility of different approaches to PWD identification and recruitment. We will also consider the rates of conversion to study participation and retention. Specifically we will report on:

- The number of PWD identified through community and secondary care, and case registers/Join Dementia Research (JDR)
- The proportion of PWD who give permission for us to check their medical records to determine eligibility to participate in the study
- The proportion of PWD who meet the eligibility criteria
- The proportion of eligible PWD who agree to participate in the study
- The proportion of eligible informal carers who agree to participate in the study
- The proportion of participating PWD and informal carers who start the intervention
- The proportion of participating PWD and informal carers who remain in the study on study completion

- The proportion of participating PWD and informal carers completing each outcome measure at baseline and twelve week follow-up

These data will primarily be quantitative although brief qualitative interviews will be completed with the clinical trials associates (CTAs) responsible for recruitment and with professionals responsible for the initial approach to potential participants to explore the feasibility and acceptability of the different approaches to patient identification.

3.3.3 Assessment of suitability and acceptability of outcome measures

We will also examine the response rates, acceptability and feasibility of outcome measures that could be used in a definitive trial. The outcome measures for different participants are described below and summarised in Table 1. We will include a small number of open questions at the final follow-up interview to explore their views on the measures used and to identify any additional outcomes of the intervention that have not been captured. The clinical researchers responsible for collecting outcome data will also be invited to take part in a brief qualitative interview to give their feedback on the outcome measures.

Table 1 Assessment of outcome measures

	Completed by	Time to complete	Baseline visit	12 week follow-up visit
MOCA	Patient	10 minutes	✓	
EQ-5D-5L	Patient	5 minutes	✓	✓
QOL-AD	Patient	5-10 minutes	✓	✓
MFES	Patient	5-15 minutes	✓	✓
GAS	Patient	20-40 minutes	✓[1]	✓[1]
DAD	Informal carer (proxy)	15 minutes	✓	✓
EQ-5D-5L	Informal carer (proxy)	5 minutes	✓	✓
QOL-AD	Informal carer (proxy)	5-10 minutes	✓	✓
HUQ	Informal carer (proxy)	20 minutes	✓	✓
ZBI	Informal carer	10 minutes	✓	✓

[1] This measure will be completed with the therapist after the initial assessment and repeated at the final intervention visit.

3.3.3.1 PWD outcome measures

- **Number of falls**

This will be assessed through prospective completion of a diary throughout the 12 week intervention. We anticipate that an informal carer will help with completing the diary when required. Participants will be asked to record whether they had any falls on each day and, if so, to describe the context and consequences of the fall. These data will be used to calculate the proportion of participants with one or more falls and the fall rate per person year.

- **Montreal Cognitive Assessment (MOCA)**

This measure will be completed at baseline only to allow us to describe the cognitive profile of participating PWD.

- **European Quality of Life Instrument (EQ-5D-5L)**

The EQ-5D-5L is a standardised instrument used to measure generic health-related quality of life [6]. It will be completed at baseline and 12 weeks by PWD with the capacity to complete the items.

- **Quality of Life–Alzheimer's Disease Scale (QOL-AD)**

The QOL-AD is a standardised instrument for measuring quality of life for PWD [7, 8]. It is a 13-item scale administered via an interview. It includes the domains of physical condition, mood, memory, functional abilities, interpersonal relationships, ability to participate in meaningful activities, financial situation, and global assessments of self as a whole and QOL as a whole. It will be completed at baseline and 12 weeks by PWD with the capacity to complete the items.

- **Modified Falls Efficacy Scale (MFES)**

The psychological consequences of falling will be determined using the MFES [9]. This is a 14-item measure of falls efficacy (or fear of falling), based on the original Falls Efficacy Scale [10]. It will be completed at baseline and 12 weeks by PWD with the capacity to complete the items.

- **Goal Attainment Scaling (GAS)**

As part of the intervention, therapists will set individualised goals with participants. The goals will be agreed with the PWD by the therapists at the initial assessment and assigned 'weights'. GAS is a method of scoring the extent to which these goals are achieved in a way that is standardised for analysis [11, 12]. Progress towards goals will be measured at the final intervention visit, allowing a numerical score to be calculated at 12 weeks.

3.3.3.2 PWD outcome measures completed by an informal carer

- **Disability Assessment for Dementia (DAD)**

The DAD is a standardised instrument measuring the functional ability of PWD in activities of daily living (ADLs) [13]. It is 40-item scale administered via an interview with a proxy. It will be completed at baseline and 12 weeks with an informal carer.

- **EQ-5D-5L Proxy**

The proxy version of the EQ-5D-5L will be completed by informal carers at baseline and 12 weeks regardless of whether or not the PWD lacks capacity. This will ensure that we have complete data for all participants for at least one version of the EQ-5D-5L.

- **QoL-AD Proxy**

The proxy version of the QoL-AD will be completed by informal carers at all time points regardless of whether or not the PWD lacks capacity. (This will ensure that comparable data is available from proxy respondents for all time points).

- **Health Utilisation Questionnaire (HUQ)**

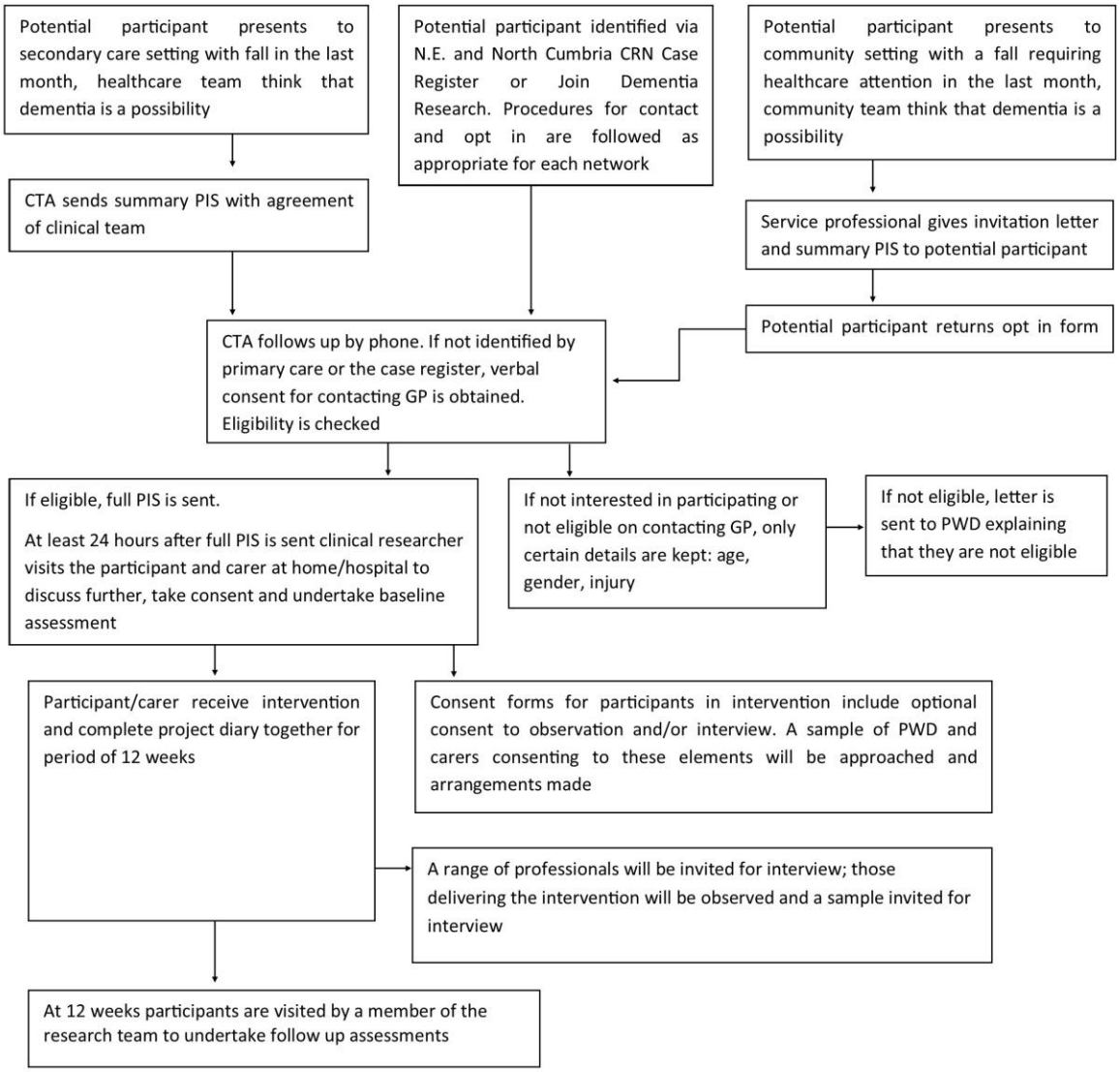
This questionnaire will be completed by the clinical researchers using information from informal carers at 12 weeks to ascertain which additional health and social care services have been used by the PWD during the twelve week period of the intervention. We will use informal carers as proxy respondents since it is unlikely that many PWD will be able to provide information about retrospective service use. To facilitate recall we have included a section for health and social care appointments in the prospective diary. This will be a pilot of the questionnaire for a future definitive trial.

3.3.3.3 Informal carer outcome measure

- **Zarit Burden Interview (ZBI)**

Carer burden will be measured using ZBI, a series of 22 questions designed to elicit the impact of the patient's disabilities on the life of the caregiver [14]. This will be completed with an informal carer at baseline and follow-up.

4 TRIAL DESIGN



5 STUDY SETTING

The study will be carried out in three research sites, reflecting a range of National Health Service (NHS) practice to allow for generalisability.

We will compare the ease of identification of PWD via three main routes; this will inform potential recruitment strategies for a future definitive trial of the DIFRID intervention.

5.1 Community settings

Three community services will be used for recruitment:

- Primary care
- Paramedics
- Telecare services

The first setting will be in primary care: patients with a known diagnosis of dementia presenting with a fall in the last month, requiring healthcare attention from any primary care professional at participating practices in the Clinical Commissioning Groups (CCGs) involved in the study.

Potential participants will also be identified by paramedics attending calls to a person with possible dementia presenting with a fall. This will apply to calls within the postcodes served by the participating CCGs.

Telecare services will also identify patients with possible dementia, resident within the postcodes served by participating CCGs, who have contacted the service about a fall requiring healthcare attention.

5.2 Secondary care settings

Three secondary care services will also identify potential study participants:

- Emergency departments
- Supported discharge teams
- Rehabilitation outreach teams

Patients with possible dementia presenting with a fall requiring healthcare attention to any of these services in participating Trusts will be eligible if they are resident within the postcodes served by participating CCGs.

5.3 Research registers

We will also recruit potential participants from the North East and North Cumbria CRN Case Register and Join Dementia Research. Participants on the Case Register have already given consent to be approached about potential research projects. Join Dementia Research is a service which allows people to register their interest in participating in dementia research and be matched to suitable studies. Those registered with either service will be eligible for the study if they have had a fall within the last month that required healthcare attention.

6 ELIGIBILITY CRITERIA

6.1 Inclusion Criteria

- A known diagnosis of dementia, made prior to entry into the study, by a specialist in dementia care (Geriatrician, Neurologist or Old Age Psychiatrist). Diagnosis must be confirmed within 2 weeks by the primary care team who will be asked to confirm that the potential participant is on the practice Quality Outcomes Framework (QOF) register of PWD, or that the person's records contain confirmed Read Codes which will result in the QOF register being updated to include this person. Appropriate Read Codes (and their equivalent International Classification of Diseases (ICD) codes) for including a person on the QOF register are given in Appendix 2.

- Must have sustained at least one fall requiring healthcare attention (via 111, district/practice nurse, or minor injuries unit as well as the services outlined in Section 5), within one month prior to their identification as a potential study participant. The fall leading to their identification will be known as the index fall. A fall will be defined as an event whereby a person comes to lie on the ground or another lower level with or without loss of consciousness.

- Must be dwelling in the community at the time of the index fall and returning to the community at the time of the intervention.

- Must have an informal carer available to assist with completion of the diaries.

- Either has capacity to consent to participation or has a personal consultee who is able to give an opinion on the participation of the PWD.

6.2 Exclusion Criteria

- Diagnosis of dementia cannot be confirmed by the primary care team within 2 weeks of their being identified as a potential participant.

- Participant found to be dwelling in residential or nursing care, or to have been a hospital inpatient at the time of the index fall.

- Participant refuses consent, or lacks capacity and does not have personal consultee, or their personal consultee declines participation.

- Not able to communicate in English either because they are not a native English speaker or due to advanced dementia.

- Informal carer declines participation in the study.

7 TRIAL PROCEDURES

7.1 Recruitment

7.1.1 Identification and recruitment of people with dementia

7.1.1.1 Community services

At the start of the study primary care practices will perform a retrospective search to identify potential participants for the study who have had a fall in the last month. They will receive an invitation letter and summary participant information sheet (PIS), explaining that they are eligible for a research study. Prospectively, all patients on the dementia QOF register will have a flag applied to their records. If a primary care consultation occurs with these patients, the professional will be alerted to determine whether the consultation is due to a fall within the last month and if so, the potential participant will be given or sent an invitation letter and summary participant information sheet (PIS), explaining that they are eligible for a research study. Potential participants will not be approached more than once about the study. We will include district and practice nurses in the Site Initiation Visits where possible to ensure that they are informed about study procedures and are prepared to discuss the study with patients who are seen at home, rather than in the surgery. Potential participants receiving the invitation letter will be invited to complete and return an opt-in form to the clinical trials associate (CTA) if they are interested in taking part.

In the other community settings (telecare and paramedics), potential participants with a history of memory problems (either self-reported; reported by an informal carer; recorded in service records; or apparent on observation) and presenting with a fall requiring healthcare attention will be given a letter and summary PIS by the relevant service, explaining that they may be eligible for a research study. They will be invited to complete and return an opt-in form to the CTA if they are interested in the study. Potential participants being taken to hospital by paramedics will be picked up by the CTA at the ED, therefore to avoid multiple contacts it will only be necessary to give the letter and summary PIS to potential participants not attending hospital. If the potential participant or carer indicates that they have already been approached about the study then the summary PIS and letter will not be given out again. Paramedics will be asked to use their discretion when considering whether to give out the summary PIS and if the person is in a distressed state then they may decide it is inappropriate to give out the summary PIS. To protect persons lacking capacity from undue stress, if a person thought to lack capacity to understand the PIS, and no carer is present to receive the summary PIS and letter then these documents will not be given.

The CTA will keep in regular contact with all participating services to ensure that they remain aware of the study and to identify and resolve any obstacles to recruitment which become apparent.

7.1.1.2 Secondary care services

CTAs embedded in the healthcare teams in each site will liaise with healthcare professionals in each of the secondary care settings (EDs, outreach rehabilitation services, supported discharge teams), to identify potential participants for recruitment. Professionals attending a person with a fall will be asked to include a question about whether it is possible that the person may have dementia. This

information may be obtained by a direct history of known dementia or confusion from the person or their informal carer, or if not available if the person appears to be confused in the opinion of the professional. All persons with possible dementia who have sustained a fall will be recorded so that the CTA embedded within the clinical team is able to send out a summary PIS. The responsibility for a decision to send the PIS would lie with the responsible clinician from the referring service. The CTA will keep in regular contact with the participating professionals to ensure that they remain aware of the study and to identify and resolve any obstacles which become apparent. The CTA at each site will make a record of any duplicates presenting via more than one route and ensure they are only approached once. A summary PIS will be sent by post to the person as soon as practicable after the person has been detected as a potential participant- this would usually be the day after the attendance at the relevant service or the Monday after attendance in the case of a weekend.

7.1.1.3 Research registers

The NE and N. Cumbria Clinical Research Network (CRN) Case Register is a database of research interested patients with a diagnosis of dementia or Parkinson's disease. NE and N. Cumbria CRN staff embedded within the clinical teams will identify potential participants from the Case Register. The initial approach will be made by phone by a member of the NE and N. Cumbria CRN who will introduce the study and check whether the person has had a fall requiring healthcare attention. If the patient has had a fall for which they sought healthcare attention and is potentially interested in taking part, their verbal consent will be sought to pass their contact details to the CTA. The CTA will then send out the full PIS and follow this up with a telephone call approximately one week later. The CTA will answer any questions and check whether they are still interested in taking part in the study having had time to consider the information in the PIS. If appropriate, a home visit will be arranged at which consent will be sought and the baseline assessment completed.

Join Dementia Research (JDR) is a national service which allows people to register their interest in participating in research and researchers to 'advertise' their project. JDR is funded by Department of Health working in partnership with the charities Alzheimer's Society and Alzheimer's Research UK and is Health Research Authority (HRA) endorsed. JDR allows potential research participants to provide information about themselves so that they can be matched to relevant research studies. When the study is registered on JDR, potentially eligible patients will receive an email informing them that they may be eligible for the study and invited to express their interest via the website. The CTA will be given log in details and will be able to view 'matches'. The CTA will initially approach patients who have expressed an interest, attempting to make contact within five working days. However, if insufficient numbers of patients express an interest, the CTA can also review other matches and make contact with patients via their preferred method (text, telephone, letter or email). Regardless of whether the patient expressed an interest or not, during this initial contact the CTA will check whether the patient has had a fall within the last month which required healthcare input. If so, the CTA will explain that we need to check the general practitioner (GP) records to confirm that the patient is eligible. The process of signing up to JDR does not require formal confirmation of diagnosis, therefore we will need to check whether potential participants are on the primary care QOF dementia register before sending the PIS. The CTA will explain that if the patient is eligible, they will be sent a detailed PIS and their contact details will be passed to the clinical researcher who will contact them in approximately one week's time to answer any questions and arrange a time to visit them at home to take consent and conduct the baseline assessment. If the

patient is not eligible, the CTA will contact the patient again as soon as possible, to explain that they do not meet the eligibility criteria for this study.

7.1.2 Identification and recruitment of informal carers

We anticipate that many PWD seeking healthcare attention will be accompanied by an informal carer. In this situation, the informal carer will be aware of the study from the outset. They will be issued with an informal carer PIS by the CTA at the earliest opportunity. This is likely to be at the point of the follow-up call to seek verbal consent from the PWD to contact their GP practice to confirm eligibility (since it is probable that the informal carer, rather than the PWD, will answer the telephone). If PWD are not accompanied by an informal carer, we will ask them to identify if they have an informal carer who provides help with day to day activities and who might be interested in being involved in the study with them. If the PWD is able to provide a name and address, the CTA will send the informal carer an invitation letter and PIS. If the PWD is able to provide a name and phone number the informal carer will be contacted for an address. If the PWD can only provide a name, the CTA will send the information addressed to the informal carer, c/o the PWD to the PWD's address.

7.1.3 Identification and recruitment of professionals

The qualitative research team will liaise with CTAs throughout recruitment to discuss progress and talk through any problems or issues. Towards the end of the study, each CTA will be invited to take part in a formal interview and sent a PIS by the qualitative team. This will be followed up by email or telephone to discuss participation and, if appropriate, arrange the interview.

Professionals involved in developing, training, supervision and delivery of the intervention will be aware that they will be expected to take part in observation and interviews as part of their role. A PIS will be provided to make these expectations clear and to outline the rationale for these qualitative aspects of the study.

The qualitative study will be introduced to members of the MDT at their initial meeting and their verbal consent will be sought to pass their contact details onto the qualitative team. They will subsequently be contacted and invited to take part in observation and/or a formal interview and sent a PIS. This will be followed up by email or telephone to discuss participation and, if appropriate, arrange the interview.

To ascertain the 'fit' of the intervention with existing services, and the impact on referral patterns, we will liaise with the MDT and staff delivering the intervention to identify where referrals have been made. Any referral letters sent as part of the intervention will explain that the recipient's details will be given to the qualitative team and that the recipient may be contacted and invited to take part in an interview. A copy of all referral letters will be sent to the qualitative team. This will enable us to identify a purposive sample of professionals to whom a referral has been made. Selected professionals will be sent an invitation letter and PIS. This will be followed up by a telephone call within a week to check whether the professional is willing to take part and, if so, to arrange a meeting to take consent and conduct the interview.

As part of their initial assessment, the physiotherapist and occupational therapist will explore current support services being used by the PWD. We will use information from the assessment to identify a purposive sample of staff whom we would like to interview. If sufficient information is available, we will directly make contact with the professional and follow this up by sending a PIS to those who are interested in taking part. If contact information is incomplete and the service is delivered in the PWD's home, the person delivering the intervention will ask the PWD and informal carer if they can leave some information for the professional. This would include an invitation letter, PIS and opt-in form. If the professional is interested in taking part, they would be asked to return the form to the qualitative team, who would then make contact to discuss participation and, if appropriate, arrange a meeting to take consent and conduct the interview.

7.1.4 Confirmation of PWD eligibility

With the exception of potential participants identified through primary care, we will have to confirm that the PWD is on the primary care QOF dementia register prior to formal recruitment to the study. After they have received the summary PIS, all potential participants will be contacted by the CTA by telephone. During the initial telephone call from the CTA to discuss participation, the CTA will seek verbal consent to contact the GP practice to check whether the person is on the dementia QOF register. For those referred directly by primary care, we will already know that the participant is on the dementia QOF register.

If the participant is on the dementia QOF register, the CTA will send a full PIS. A clinical researcher will contact them again to confirm eligibility and, if still interested, to arrange a home visit to take consent and undertake a baseline assessment if appropriate. Participants who are not on the dementia QOF register will be sent a letter explaining that they are not eligible but thanking them for their interest in the study.

At each stage of the recruitment procedure the CTA will keep a list of all potential participants who have had contact with the research study. If the person has declined or not responded to a contact from the research team or not been recruited for another reason then they will not receive any further contacts from the research team.

7.2 Consent

Participants will be required to give informed consent to participation in the intervention study in accordance with the Declaration of Helsinki. Due to the nature of dementia, some participants may lack the capacity to give full informed consent. In this case the provisions of the Mental Capacity Act (2005) will apply. PWD will be asked to give consent appropriate to their level of understanding, ranging from written informed consent to account being taken of verbal and non−verbal communication in determining willingness to participate. In those individuals found to be without capacity to give full informed consent, the CTA will identify a personal consultee and seek their advice regarding participation. Personal consultees will be given or sent a letter explaining the role of a consultee. If the consultee is not present at a home visit then they will be contacted by telephone by the clinical researcher to ascertain their advice about the person's participation. If a consultee thinks that the person would not have wanted to participate in the study the participant

will not be recruited and they will not be contacted any further about the study. If they do not give an opinion it will be assumed that consent is withheld and they will not be recruited or contacted further about the study. Any PWD appearing distressed by participation or withdrawing consent will be excluded from the study without prejudice to clinical care.

Consent will be sought from all professionals with the exception of those involved in developing, training and supervising the intervention and those directly involved in delivering the intervention. Participation in observation and/or interviews and informal discussions will be part of their role and therefore not optional (they will be provided with a PIS to make these expectations explicit).

7.3 Baseline Assessments & Data

Baseline data will be recorded by a clinical researcher for PWD and informal carers consenting to the intervention study within two weeks of confirmation of eligibility. For PWD, this will include the MOCA, EQ-5D-5L, QoL-AD and MFES (Table 1, page 24). Informal carers will be asked to complete QOL-AD Proxy, EQ-5D-5L Proxy, DAD, and ZBI (Table 1).

After the baseline assessment, the clinical researcher will send a referral to the intervention team using a structured referral form with details of the baseline assessments of the PWD and informal carer. The intervention team will then arrange an initial intervention assessment within 2 weeks (see section 8.1).

7.4 Follow up Assessments

At 12 weeks, the clinical researcher will carry out a second visit to repeat most of the outcome measures completed at the baseline assessment with PWD and informal carers (see Table 1). The exception is the MOCA; completing this at baseline will enable us to describe the cognitive function of participating PWD, but it will not be repeated as the intervention is not expected to have an impact on cognition. The HUQ will be completed by the clinical researcher with the informal carer on behalf of the PWD to determine the use and health and social care services by the PWD in the preceding 12 weeks[16].

7.5 Quantitative assessment of intervention delivery

PWD consenting to the intervention study will be asked to complete a prospective diary for 12 weeks, with the assistance of their informal carer. The diary will be used to record:

- falls
- compliance with activity recommendations between therapy sessions, and
- service use.

To minimise participant burden, we will ask participants only to jot down service use that is different to their usual support package. For example, if they usually receive home care twice a day, they would not need to record this, but would note down if, for any reason, there was a change to the number of sessions. We would also ask them to note when they started any new additions to their

package of care, for example, attendance at a lunch club. This information will be used in the final assessment to facilitate recall when completing the HUQ.

Further information on intervention delivery and fidelity will be obtained through analysis of intervention documentation, including notes of assessment and ongoing therapy sessions, referrals, and records of MDT meetings.

7.6 Qualitative assessment of intervention delivery and study procedures

The initial consent process with PWD and informal carers will include consent for optional participation in the qualitative aspects of the study. We will purposively select a sample of consenting PWD and informal carers for observation and interview. Examples of participant characteristics which will be considered when sampling will include: gender; falls history; goals and activities identified for the intervention; intensity of the intervention; and adherence to the intervention (through participant diaries and discussions with the therapists delivering the intervention). We will aim to observe the delivery of all components of the intervention in all sites assuming this is logistically possible. This will enable us to explore whether and how: the sessions are tailored to individuals; activities are embedded into usual routines; and the role of the informal carer in the intervention.

Interviews will explore the acceptability and perceived value of the intervention to PWD and their informal carers. We will also explore the extent to which participants felt the intervention was tailored, their views on the intensity of the intervention and staff involved in delivering the intervention, and any suggested changes to the intervention. PWD consenting to a qualitative interview will be interviewed separately from their informal carer where possible, but jointly if preferred by the participant. Interviews will take no longer than 60 minutes and will be audio recorded with participants' permission (as documented on the initial study consent form; consent to recording will be verbally confirmed at the time of the interview). The clinical researcher undertaking baseline and follow-up assessments will include some open-ended questions to explore participants' views on the outcome measures. These qualitative data will be recorded in detail on the case report form (CRF) and passed to the qualitative team for analysis.

As described above professionals will be observed during intervention delivery (with the consent of the PWD and informal carer) and during MDT meetings. The qualitative team will also observe the initial training and some supervision sessions. The importance of observing supervision was highlighted in a previous study where it revealed specific areas in which additional training was required [15]. Information from the observation will inform subsequent interviews and informal discussions with professionals and will allow us to follow up emerging issues in more detail. Interviews with MDT members will explore the perceived value and sustainability of the MDT meetings as part of the intervention. Alternative models of obtaining specialist input will also be explored.

Interviews with professionals to whom PWD and/or informal carers have been referred as a result of the intervention and/or who have been providing care to participants during intervention delivery will explore their experiences of the intervention; the 'fit' of the intervention with the care they

provide; and suggested changes or improvements to the content, delivery or timing of the intervention. The appropriateness of referrals will also be explored.

Table 2 Schedule of Events

	Baseline assessment (clinical researcher)	Week 1 (intervention)	Weeks 2-12 (intervention)	Week 12 follow-up assessment (clinical researcher)
Informed consent (including consent for observation and/or interview)	X			
Baseline data collected (see Table 1)	x			
2 Assessment visits by Intervention team including Timed Up and Go Test		X		
Up to 22 visits by Intervention team Final visits will include Goal attainment scaling and Timed Up and Go test			X	
Completion of diary		X	X	
Informed consent of professionals and participants and observation of interventions received		X	X	
Informed consent and qualitative interview with some professionals regarding views on intervention.			X	
Qualitative interview with patients, informal carers and professionals views on intervention (subset of participants who consent to qualitative study)			X	

Follow up outcome data collected				X

7.7 Withdrawal Criteria

PWD and informal carers will have the right to withdraw from any/all aspects of the study at any time without having to give a reason. Investigator sites should try to ascertain the reason for withdrawal and document this reason within the CRF and participant's medical notes. PWD and informal carers will be able to withdraw from the (optional) qualitative component, intervention delivery and/or outcome assessment. Investigator sites will clarify with participants which aspects of the study they wish to withdraw from and will document this on a study withdrawal form.

The Investigator may discontinue a participant from the study at any time if the Investigator considers it necessary for any reason including:

- Participant withdrawal of consent
- Significant protocol deviation or non-compliance
- Investigator's discretion that it is in the best interest of the participant to withdraw
- An adverse event (AE) that renders the participant unable to continue in the study
- Termination of the study by the sponsor.

Due to the nature of the disease some participants may become very ill or die before completion of the study. Participants who withdraw from the trial will not be replaced routinely, but if an unexpectedly large number of participants withdraw early it may be necessary to replace them to achieve adequate data to answer our research questions.

Professionals who are not directly involved in intervention supervision or delivery will also have the right to withdraw from the study at any time without having to give a reason.

7.8 End of Study

The end of the study will be defined as the completion of all data collection.

8 DIFRID INTERVENTION

8.1 Description of the DIFRID Intervention

The intervention will be a multidisciplinary intervention primarily delivered in the participant's home. The intervention will be tailored to the abilities of the participant, their likes and dislikes for activities and goals agreed between the therapist and the participant and their informal carer. The number of sessions will be tailored to the needs of the participant; the first two sessions will be assessment sessions followed by up to 22 therapy sessions delivered over a total period of 12 weeks. The assessment and therapy procedures will be described in a manual for professionals.

8.1.1 Training

Training sessions in working with PWD and use of the manual will be delivered to professionals responsible for intervention delivery prior to enrolment of the first participant. Training will be delivered by a physiotherapist and occupational therapist with expertise in working with PWD. They will be supported by a qualitative researcher who will describe elements of good practice identified from WP2. Training will include:

- Dementia awareness
- Dementia identification, assessment and diagnosis
- Dementia risk reduction and prevention
- Person-centred dementia care
- Communication, interaction and behaviour in dementia care
- Health and well-being in dementia care
- Assessment and management of pain
- Pharmacological interventions in dementia care
- Living well with dementia and promoting independence
- Families and carers as partners in dementia care
- Equality, diversity and inclusion in dementia care
- Law, ethics and safeguarding in dementia care
- End of life dementia care
- Research and evidence-based practice in dementia care

8.1.2 Assessment sessions

Both a physiotherapist and an occupational therapist will visit the participant during week 1. They will complete a structured holistic assessment proforma which will assess the items given below. Assessment will include the perspectives of both the participant and the informal carer and discussion with professionals already involved with the participant.

- History and circumstances of index fall and any injuries sustained
- Details of treatment offered so far and services already involved
- Past medical history and comorbidities
- Medication

- Osteoporosis risk
- Living arrangements
- Details of current informal and formal carer input
- Current levels of activity, routines and likes and dislikes for activities
- Current mobility (bed mobility, bed and chair transfers, walking and stairs)
- Assessment of risk factors for falls
    - Fear of falling
    - Dizziness
    - Nutrition and fluid intake
    - Pain
    - Continence
    - Footwear
- Identification of challenging behaviours and sleep disturbance
- Identification of informal carer stress
- Identification of informal carer's willingness to be involved in promoting the activities
- Physiotherapy examination
    - Objective body examination including focus on areas of pain
    - Range of movements
    - Assessment of muscle strength
    - Timed Up and Go test
    - Use of walking aids
    - Functional movements e.g. reaching, carrying and bending
    - Lying and standing blood pressure
    - Visual assessment
- Occupational therapy examination
    - Functional assessment
    - Assessment of home safety environment including a walk around the home to see where actual falls have occurred
    - Assessment of functional activities e.g. ability to make a cup of tea
    - Assessment of home adaptations and need for new adaptations

At the end of the assessments a problem list will be compiled and a set of goals to be achieved will be agreed with the participant and their informal carer. The problem list and goals will then be discussed at a multidisciplinary team (MDT) meeting. An action plan including recommendations for activities to be carried out during therapy sessions will be formulated. One therapist will be identified as the participant's key worker. The goals and action plan will be reviewed and adjusted by the key worker if necessary at week 6.

The MDT will also identify the need for any onward referrals including to the GP, geriatrician, mental health nurse, old age psychiatrist, continence adviser, podiatrist, optician or dietitian.

For informal carers, the initial intervention assessment will include an exploration of their capacity and willingness to take part in the intervention, and their knowledge and understanding of dementia and falls (including attitudes to risk) and an assessment of carer stress (using the data from the Zarit

Burden Interview as a guide). The needs of informal carers, and how to address these, will also be considered during by the MDT and an action plan made where appropriate.

8.1.3 Therapy sessions

Up to 22 x 60 minute therapy sessions will be delivered over a total period of 12 weeks. The number and frequency of sessions will be tailored to the needs of the participant. For example, sessions could be delivered in a tapered format, e.g. 2-3 sessions per week for 8 weeks then weekly thereafter, or delivered evenly over the period of 12 weeks. If the participant is making good progress and wishes to continue the activities themselves they may have fewer than 22 sessions. Up to 3 sessions will be delivered by an occupational therapist and up to 3 sessions by a physiotherapist with the remaining sessions being delivered by a rehabilitation support worker.

Prior to each activity session attention will be paid to the comfort of the participant, including nutritional needs and assessment of pain (using tools to assess non-verbal signs of pain if appropriate). Activities will include both physical exercises and functional activities. Physical exercises will include strength and balance exercises and dual task exercises. Participants will be offered a choice as to whether to follow an exercise programme separate from their daily activities or whether to embed these in their daily life e.g. practising balance exercises while standing at the sink washing up. Functional activities to be included will be identified during the goal setting process and these will include encouragement to engage in community and social activities such as shopping and attending local groups. Informal carers will be encouraged to become involved in the goal setting process and in promotion of the activities, joining in with activities where appropriate. The recommendations for activity at each visit will be supported with participant literature including pictures of physical exercises to be carried out. Participants will be encouraged to undertake increased activity throughout the day and cueing cards will be used to embed activities in daily life. A record of the activities undertaken at each visit and recommendations for activities to be performed by the participant between visits will be made using a structured proforma for each visit. The proforma will also include a review of whether the participant undertook the recommendations since the previous visit. If the participant has not adhered to the recommendations the reasons for this will be explored with the participant and goal setting will be reviewed.

Depending on the needs, abilities and preferences of the participant they may also be referred to other local services available for people who fall such as Staying Steady groups. After the final therapy visit the GP will be sent a summary of the interventions carried out by the intervention team and recommendations regarding ongoing service input where needed.

8.2 Adverse events

This is a non-drug intervention trial, using interventions that might be offered as part of a routine physiotherapy intervention. Dementia is progressive and associated with comorbidity. Inter-current illness will be very common. We will aim to achieve a balance between ensuring that any adverse events (AEs) which are likely to be related to the study are detected, and the recording of numerous unrelated events.

8.2.1 Adverse events

Falls, injuries, deaths and hospital admissions will be ascertained prospectively throughout the study. They will be recorded through diaries which will be reviewed regularly by the therapists and/or rehabilitation support workers.

We will define an AE as an incident, injury or symptom related to therapy sessions, or activities undertaken independently. The most likely AEs are fatigue, minor musculo-skeletal symptoms or injuries such as muscle stiffness, or sprains, or increased falls though increased activity. Some conditions such as arthritis or angina may be exacerbated by exercise. AEs will be monitored by therapists and rehabilitation support workers, and reported where they occur.

8.2.2 Serious adverse events

A distinction is drawn between serious and severe AEs. Severity is a measure of intensity, whereas seriousness is defined using the criteria below. Hence, a severe AE need not necessarily be serious. We will define a serious adverse event (SAE) as any adverse event that:

- Results in death
- Is life-threatening
- Requires hospitalisation
- Results in persistent or significant disability or incapacity.

Expected co-incidental or co-morbid events, given the frailty of the participant population include: chest infections; pneumonia; strokes; renal failure; urinary tract infections; increased confusion; delirium. We will record any event that results in contact with healthcare professionals or hospital admission. Mortality may also be expected for some participants given their age and frailty at the point of commencing the study; all deaths will be recorded.

8.2.3 Causality

a) Not related or improbable: a clinical with temporal relationship to trial intervention which makes a causal relationship incompatible or for which other treatments, chemicals or disease provide a plausible explanation. This will be counted as “unrelated” for notification purposes.

b) Possible: a clinical event, with temporal relationship to trial intervention which makes a causal relationship a reasonable possibility, but which could also be explained by other interventions, chemicals or concurrent disease. This will be counted as “related” for notification purposes.

c) Probable: a clinical event, with temporal relationship to trial intervention which makes a causal relationship a reasonable possibility, and is unlikely to be due to other interventions, chemicals or concurrent disease. This will be counted as “related” for notification purposes.

d) Definite: a clinical event, with temporal relationship to trial intervention which makes a causal relationship a reasonable possibility, and which can definitely not be attributed to other causes. This will be counted as “related” for notification purposes.

e) Not assessable: there is insufficient or incomplete evidence to make a clinical judgement of the causal relationship.

The Chief Investigator (CI) will review each AE to determine whether an AE is serious, expected or causally-related. With regard to the criteria above, the CI will draw on their medical and scientific judgement to decide whether prompt reporting is appropriate in that situation.

8.2.4 Reporting procedures

All adverse events should be reported. Depending on the nature of the event the reporting procedures below should be followed. Any questions concerning AE reporting should be directed to the CI in the first instance.

Non-serious AEs: All such events, whether expected or not, should be reported by the therapist to the clinical research team.

Serious AEs: An SAE form should be completed and faxed by the therapist to the CI within 24 hours. However, hospitalisations for elective treatment of a pre-existing condition do not need reporting as SAEs.

All SAEs should be reported to the NHS Research Ethics Committee (REC) where in the opinion of the CI, the event was:

- 'related', i.e. resulted from the administration of any of the research procedures; and
- 'unexpected', i.e. an event that is not listed in the protocol as an expected occurrence

9 ANALYSIS

9.1 Analysis Population

All analyses will be conducted on an intention to treat basis, with sensitivity analyses used to investigate the impact of removing individuals who did not receive the intervention as allocated.

A subset of these participants and their informal carers will take part in the interview part of the study.

Professionals will also be observed delivering the intervention; some of those observed will be invited to take part in a qualitative interview.

Professionals in related services will be invited to take part in a qualitative interview.

9.2 Quantitative analyses

The outcomes are feasibility outcomes. We will report the numbers of eligible participants seen over the recruitment period, and the resulting rates of recruitment, retention, and data completion. Non completers will be characterised. We will also assess performance of potential outcome measures for a definitive trial. We will ascertain data completeness of the instruments and any potential bias in the completion of follow-up data to inform the choice of instruments in a future trial. The majority of the outcome data will be presented in simple descriptive tables presenting percentages, means and standard deviations. This information will be used to inform the design of the future definitive trial.

Participant characteristics will be presented as summary statistics. Our main focus will be on completion rates of the diaries and other outcome measures. Specific questions to be answered are:

- Did recruitment adhere to target at each site?
    - Total numbers of recruitment at each site will be compared with the target of 10 participants per site.
- What factors influenced eligibility and what proportion of those approached were eligible?
    - Presentation rates of potentially eligible participants will be calculated for each setting and compared between sites. Reasons for non-eligibility will be categorised and the proportion who are eligible will be calculated, giving an estimate of the potential future demand for this intervention within the NHS.
- Did participants consent?
    - The proportion of potentially eligible participants consenting to initial contact and then to full participation in the study will be calculated, giving an indication of likely recruitment rates to any future randomised clinical trial.
- Did professionals adhere to the study manual?
    - This will be assessed quantitatively by comparing the number of sessions delivered with the target number of 2 assessment visits and 22 therapy sessions (or fewer if tailored). Reasons for non-adherence to target e.g. due to appropriate tailoring of

the intervention will be recorded. This question will also be considered qualitatively as described below.

- Did participants adhere to the intervention?
    - The proportion of participants adhering to at least 75% of planned exercise sessions between therapy visits will be assessed using participant diaries (exercise component). This question will also be considered qualitatively as described below.
- Were outcome assessments completed using the diaries and data collection tool?
    - We will look at the overall response rates and the completion of participant diaries (falls component) used to obtain the primary outcome for a future RCT. Number of fallers/ non-fallers and fall rate per person year will be calculated.
    - We will look at the overall response rates and the completion of each outcome measure detailed below in the data collection tools. This will help us identify potential issues (if any) with the data collection tools and amendments can be made accordingly.

9.2.1 Health Economic data

The data collected during WP4 will be analysed and presented as completion rates and descriptive statistics; this will allow our results to be used for meta-analysis and systematic reviews. As part of WP2 a healthcare utilisation questionnaire (HUQ) was developed and piloted – the format and administration of this questionnaire was adapted in light of the responses and feedback from WP2. The questionnaire will now be completed once by the clinical researcher at the 12 week follow-up visit with information provided by the informal carer. The clinical researcher will make notes on the CRF regarding the perceived value and burden of including space in the participant diary to make a note of services received as an aide memoire for completing the HUQ at the end of the study. These notes will be passed to the qualitative team for analysis.

The data will be analysed as completion rates and descriptive statistics. We will look at the overall response rates and the completion of each question in the data collection tools (HUQ and EQ-5D-5L). This will help us identify any potential issues with the data collection tools and suggest amendments for a future definitive trial. Descriptive statistics will be provided for each type of healthcare resource reported and will be presented as the mean number of visits and standard deviation.

We will also determine the feasibility of identifying and estimating costs associated with the intervention and resource use. Intervention costs will be based on the data provided by the therapists on number of sessions, travelling time, referrals and involvement of the MDT. This will determine the ease of cost collection for a full definitive trial.

9.3 Qualitative Analyses

Field notes of observation and interview transcripts will form the formal data for analysis. Normalisation Process Theory (NPT)[17] will inform both data collection and analysis. This theory is increasingly being used in studies of the implementation of interventions in health care (www.normalizationprocess.org) including published studies from current applicants [15, 18, 19]. Normalization process theory is valuable in highlighting whether problems with implementation reflect a lack of perceived relevance of the intervention (coherence); the unwillingness of

participants to invest in the intervention (cognitive participation); difficulties in delivering the intervention, such as a lack of resource or shortfalls in skills and knowledge (collective action); or a lack of feedback on the impacts of the intervention or inability to adapt the intervention to meet local needs (reflexive monitoring). Identifying key barriers to implementation using NPT helps in deciding how best to optimise an intervention and associated training and documentation prior to further implementation.

All field notes and interview transcripts will be anonymised prior to analysis. Following the principles of the constant comparative method, data analysis will proceed alongside data collection. This will ensure that emerging themes and issues can be explored in subsequent data collection. The qualitative team will use data analysis workshops to consider data from different sources (observation; interviews with different stakeholders, informal discussions) and develop a coding frame. Some data analysis workshops will also include members of the extended team to offer different perspectives on the data. Once a coding frame has been agreed, we will use NVivo software to manage data analysis. The specific analyses relating to WP4 will focus on issues of feasibility and acceptability of the intervention and will explore the extent to which views on the intervention are consistent within and between stakeholder groups.

On completion of WP4 analyses, we will conduct an integrative analysis of data from WP2, WP3 and WP4 to finalise the realist review. This will allow us to refine our CMOcs in light of the findings of the feasibility study. To synthesise data from different WPs, we will develop a common coding frame, accepting that some codes may be more pertinent to some datasets than others. Our previous experience has shown that coding in this way illuminates difference or absence within the data.

9.4 Final Recommendation

The final recommendation will synthesise both the qualitative and quantitative findings from WP4. The report will identify any factors which would be likely to make a future trial unfeasible. If a trial is feasible we will make a recommendation as to the optimum design and setting for the trial and discuss potential facilitators and barriers to its completion. Where barriers are identified, we will describe any recommended changes to the procedures and manuals used in WP4.

9.5 Sample Size Consideration

Formal sample size calculations are not necessary for feasibility and pilot studies. The sample size for the intervention study was decided by the expert consensus panel. It is anticipated that 10 participants per site will give us sufficient data to answer feasibility questions including estimation of potential recruitment rates, intervention adherence and rates of completion of data outcome tools.

In terms of qualitative data, we will aim to interview up to five patient/informal carer dyads in each site. However, our experience in WP2 suggests that achieving a 50% response rate for interviews is unlikely. Participants have generally been more willing to consent to observation than interview, and we will try to maximise data collection using a combination of these methods. The interviews will be scheduled at different points in the intervention since this will facilitate recall of specific components by PWD. If feasible within the timeframe, we will schedule some interviews on completion of the

intervention to gain a holistic view since participants' understandings of and views towards intervention components (e.g. assessment) may change over time as the purpose of such activities becomes more apparent. We will interview up to ten professionals responsible for supervising or delivering the intervention; interviews will take place throughout WP4 to enable comparison of their views at the beginning and end of the feasibility study and explore whether and how implementation of the intervention has changed over time. Depending on the number of professionals involved in delivering the intervention in each site, we may conduct focus groups rather than interviews as this will be a more effective use of resources. Interviews will also be conducted with up to six members of MDTs across all sites and up to six professionals in related services (two in each site). We will also conduct brief interviews with the CTA and clinical researcher at each site to obtain feedback on the recruitment processes and outcome measures.

10 DATA HANDLING

10.1 Data Collection Tools and Source Document Identification

Data will be handled, computerised and stored in accordance with the Data Protection Act 1998. All original consent forms will be securely held in the investigator site files (ISFs), with copies in the Trial Master File (TMF) held at Newcastle University, the primary care clinical notes and a copy given to the participant. Copies sent to Newcastle University will be scanned and sent by secure NHS.net email. Caldicott approval will be obtained as part of local NHS permission from each site to enable the collection of personal identifiable information as part of this trial. The quality and retention of study data will be the responsibility of the CI. All study data will be retained in accordance with the latest Directive on GCP (2005/28/EC) and local policy.

10.1.1 Screening logs

A CTA in each site will maintain the screening log. The lists of potential patients from secondary care will include NHS/hospital number, date of birth and name and contact details to facilitate retrieval of notes and enable us to send or provide information about the study. This information will be recorded in the Investigator Site File and kept in a password protected file on a NHS Trust computer. The Investigator Site File will be stored in a locked room. Each patient will be allocated a unique study identifier. All data extracted from the case notes and recorded for the study will be identified only by the unique study identifier. The diagnosis of known dementia will be confirmed by the patient being on the primary care dementia QOF registers. Where the patient is not on the dementia QOF register but other information suggests they should be the GP will be asked to review the patient's Read codes and advise whether they believe the register should be revised to include the patient. For those who do not consent to be in the intervention study the only data to be retained by Newcastle University will be age, gender, confirmed diagnosis of dementia if confirmed and type of injury, if injury is present. For those non participants no patient identifiable information will be retained.

10.1.2 Outcome measures

Data on the standardised outcome measures will be collected on paper Case Report Forms (CRFs) by clinical researchers. Data for the health economics component (HUQ) will be integrated into the CRFs. Diaries will be returned to the research team at the end of the intervention. Data from the CRFs and diaries will then be entered on to a bespoke database with an auditable data trail. The database will be held on a secure server maintained by Newcastle University and access will be password protected.

10.1.3 Intervention delivery (quantitative data)

The intervention will be delivered according to the manuals developed in WP3. Intervention documentation will be designed to facilitate collection of clinical data relevant to each component of the intervention. Clinical staff will use structured proformas to record the baseline assessment and delivery of each component of the intervention at subsequent intervention visits. Intervention records will be returned to the research team for data extraction by secure courier services. Data

will be extracted using a unique identifier and entered on to a bespoke database for analysis with an auditable data trail. The database will be held on a secure server maintained by Newcastle University and access will be password protected.

10.1.4 Qualitative data

Topic guides will be used for interviews (and focus groups if these prove practicable) (Appendix 4). Some interviews (and focus groups) with professionals may explore a particular case in detail to understand whether and how the DIFRID intervention was integrated with other services. Interviews (and focus groups) will be audio recorded with participants' permission and transcribed for analysis. All audio-recordings of interviews, focus groups and informal discussions will be transcribed, checked and anonymised. Non-anonymised voice recordings or transcripts will be handled only by the qualitative team and transcribers who have signed appropriate confidentiality agreements. Audio-recordings of training, MDT meetings or intervention delivery will be listened to by a qualitative researcher and summarised in anonymised field notes. Selected sections may be transcribed in full for more detailed analysis and to illustrate key points.

Non-participant observation will be used, with the option of audio-recording sessions in situations where the presence of a researcher is not feasible (e.g. it may not be possible for a member of the qualitative team to observe all training sessions in all sites). Details of observation will be recorded in anonymised field notes as closely as possible in time to the period of observation since this facilitates recall. Informal discussions with professionals will allow us to briefly explore key issues immediately after observation. The researcher will also write a reflective diary containing details of issues to follow up, ideas for further data capture and initial thoughts on analytic themes. All data collected for the process evaluation will be stored on a secure, password protected computer network maintained by Newcastle University.

10.2 Access to Data

The study will abide by the Data Protection Act 1988. Exposure to identifiable patient data will be kept to a minimum, and all research staff will have signed a patient confidentiality statement as part of their main employment, honorary contract or acceptance by the NHS Trust.

10.3 Archiving

Archiving will be in line with Sponsor guidelines. Any paper documentation, including the master file will be archived in a secure archive facility. Other research data which is not kept as paper copies will be stored on a secure server.

11 MONITORING, AUDIT & INSPECTION

Monitoring of study conduct and data collected will be performed by a combination of central review and site monitoring visits to ensure the study is conducted in accordance with GCP. Study site monitoring will be undertaken on behalf of the study Sponsor by the NCTU, in agreement with the CI. The main areas of focus will include consent and essential documents in study files. A monitoring plan will be written, agreed and signed by the Sponsor and monitor.

Site monitoring will include:

Original consent forms will be reviewed as part of the study file. The presence of a copy in the GP notes will be confirmed for all PWD.

Original consent forms will be compared against the study participant identification list.

The presence of essential documents in the ISF and study files will be checked.

Source data verification of eligibility for all participants entered in the study.

Central monitoring will include:

All applications for study authorisations and submissions of progress reports will be reviewed for accuracy and completeness before submission.

All documentation essential for study initiation will be reviewed before the site is authorised and approved to start.

Copies of consent forms will be checked to ensure they have been completed correctly.

All monitoring findings will be reported and followed up with the appropriate persons in a timely manner.

The study may be subject to inspection and audit by NHCT under their remit as Sponsor, and other regulatory bodies to ensure adherence to GCP. The investigator(s) / institutions will permit trial-related monitoring, audits, REC review and regulatory inspection(s), providing direct access to source data/documents.

The trial may be subject to audit by representatives of the Sponsor or regulatory inspection. Each investigator site will permit trial-related monitoring, audits and regulatory inspection including access to all essential and source data relating to the trial.

The trial may be prematurely discontinued on the recommendation of the Trial Oversight Committee, Sponsor, or regulatory authority.

12 ETHICAL AND REGULATORY CONSIDERATIONS

The study will be sponsored by The Newcastle upon Tyne Hospitals NHS Foundation Trust. A formal agreement between the Sponsor and each participating site, setting out the responsibilities of

Sponsor, CI, and Site, including site Principal Investigator (PI), will be in place prior to site initiation. Evidence of local approvals including NHS organisation Research and Development (R&D) and Caldicott Guardian will be obtained prior to site initiation.

The study overall will be managed by a Programme Management Group (PMG) comprising the co-investigators and chaired by the CI. The CI will have day to day oversight of the project, while the qualitative aspects will be managed by a Senior Research Associate (SRA). Milestone progress will be reviewed on a weekly basis by the CI and SRA, together with project staff, with action taken in tandem with the steering group if any deviation from milestones is anticipated. The PMG will meet in full at least quarterly throughout the course of the project.

A Trial Oversight Committee (TOC) with 75% independent membership will provide overall supervision for a trial on behalf of the Trial Sponsor and Trial Funder and to ensure that the trial is conducted to the rigorous standards set out in the Department of Health's Research Governance Framework for Health and Social Care and the Guidelines for Good Clinical Practice (GCP).

12.1 Research Ethics Committee Review and Reports

The CI will obtain a favourable ethical opinion from an NHS Research Ethics Committee (REC) prior to the start of the trial. All parties will conduct the trial in accordance with this ethical opinion.

The CI will notify the REC of all required substantial amendments to the trial and those non-substantial amendments that result in a change to trial documentation (e.g. protocol or patient information sheet). Substantial amendments will not be implemented until this REC favourable opinion is obtained. The CI will notify the REC of any serious breaches of GCP or the protocol or urgent safety measures that occur during the trial.

An annual progress report will be submitted each year to the REC by CI until the end of the trial. This report will be submitted within 30 days of the anniversary date on which the original favourable ethical opinion was granted.

The CI will notify the REC of the early termination or end of trial in accordance with the required timelines.

12.2 Peer Review

The study has undergone peer review as part of the funding process.

12.3 Public and Patient Involvement (PPI)

The research question addressed in this call was identified by the HTA with patient and public involvement. We have shared the brief and plans for this project with older people and informal carers of PWD participating in Voice North - an organisation to facilitate the involvement of the public in research and product and service development. Voice North exists to harness the skills and experience of the public - currently over 1000 people are involved from across the North East. The participants concurred with the HTA's view that this is an important area for research into the care of PWD. Two participants were informal carers of PWD and one had experience of caring for their

father following a fall and fractured neck of femur. The participants identified that the views of people who have been recent informal carers of PWD are often overlooked in this area of health care and identified them as potential sources of learning.

The progress of this study will be overseen by a project management group and this group includes a person with Parkinson's disease and an informal carer of a PWD. They will be invited to contribute to any educational interventions developed as part of the pilot intervention. PWD and informal carers will be invited to participate in the preparation and execution of the dissemination plan, and presentation to PPI groups will be a major focus of the dissemination plan. Members of Voice North with personal experience of caring for a person with dementia have reviewed the WP4 study documentation for participants (draft information sheets, consent forms and diaries).

12.4 Regulatory Compliance

The trial will be conducted in accordance with the Research Governance Framework. Before any site can enrol participants into the trial, that site must have received NHS HRA approval or social care approval, whichever is appropriate to the site.

12.5 Notification of Serious Breaches to GCP and/or the Protocol

A serious breach is a breach which is likely to effect to a significant degree –

(a) the safety or physical or mental integrity of the subjects of the trial; or
(b) the scientific value of the trial.

The sponsor must be notified immediately of any incident that may be classified as a serious breach. The CI will notify the REC within the required timelines in accordance with the sponsor standard operating procedure (SOP).

12.6 Data Protection and Patient Confidentiality

Personal data will be regarded as strictly confidential. All data retained at site will be identified by a unique Study ID. A Participant Identification Log will be the only document retained within the ISF which contains full details of hospital number, patient name and study ID. This is essential for participant identification and verification. The only personnel with access to this will be named on the delegation of duties document. All personnel are qualified and trained in, and will comply with ICH GCP. Justification for any electronic transmissions of data will be covered in the Caldicott application approved by Sponsor.

The study will comply with the Data Protection Act, 1998. All study records and ISFs will be kept at site in a locked filing cabinet with restricted access at each site.

12.7 Indemnity

The Sponsor has liability for clinical negligence that harms individuals toward whom they have a duty of care. NHS Indemnity covers NHS staff and medical academic staff with honorary contracts conducting the trial for potential liability in respect of negligent harm arising from the conduct of the study at site.

Newcastle University will provide indemnity for non-NHS sites.

12.8 Amendments

It is the responsibility of the Research Sponsor to determine if an amendment is substantial or not and study procedures must not be changed without the mutual agreement of the CI, Sponsor and the TOC.

Substantial amendments will be submitted to the REC and HRA and will not be implemented until this approval is in place. It is the responsibility of the CI to submit substantial amendments.

Non-substantial amendments may be made at any time with a record of the amendment held in the TMF. Any non-substantial amendment that requires an update to the trial documentation will be submitted to the REC for acknowledgement of the revised version of the document.

Substantial amendments and those minor amendments which may impact sites will be submitted to the HRA for notification to determine if the amendment affects the NHS permission for that site. Amendment documentation will be provided to sites by the CI.

12.9 Access to the Final Dataset

Access to the final trial dataset will remain with the Newcastle University research team.

13 DISSEMINATION POLICY

Our communication plan is designed to achieve maximum impact for our work among clinicians, patient groups and researchers, and so in addition to academic channels we will partner with the Alzheimer's Society and Dementia UK to develop the public/patient message. This has been critical in our previous projects in the field. The study website https://research.ncl.ac.uk/difrid/ summarises the WPs to be undertaken and provides public information regarding their progress and findings. A lay summary of the findings of each WP is added to the website as each WP is completed.

For patients and members of the public, we produce a project newsletter which will be made available to participants, uploaded to the study website and made available in newsletters provided by voluntary organisations (Alzheimer's Society, Age UK). We will present our findings to local PPI groups.

For researchers and professionals, the systematic review in WP1 is registered on the PROSPERO database of systematic reviews and has been submitted for publication. We will also use our multidisciplinary links to publicise the findings on relevant professional websites (e.g. the British Geriatrics Society). Further links have been established as part of the WP1, where we surveyed current practice. We will disseminate the results of our study to identified links and signpost them to our website. The findings of each WP will be presented at scientific meetings and published in peer-reviewed journals. We will target open access publications to maximise availability. We will aim to present at 2 Conferences for example at the BGS and American Geriatric Association meetings.

For policy makers and commissioners, we will publish articles in appropriate periodicals and journals and provide signposting to our website. We will use our links in the Dementia Action Alliance and other voluntary organisations to identify key policy groups.

Social media- we will use Twitter to provide relevant details of any new publication, website update or new blog that the project completes. To gauge feedback, we will send a tweet that links to a research blog and ask our followers for their feedback and comments. The Twitter feed of the university media department will be part of our communication package.

Finally, the findings of the research will be reported in the NIHR HTA Journal, describing whether it has been possible to design an intervention to improve outcomes for community dwelling PWD with fall related injuries. If it has been possible to design such an intervention, we will describe how recipients should be identified, describe and manualise the key components of the intervention, recommend how and where it should be delivered, and by whom. We will describe the learning needs of the professionals delivering the intervention and produce appropriate educational materials.

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15 APPENDICES

15.1 Appendix 1 Summary of Consensus Statements from the Expert Panel

Statement	Outcome	Round	Percentage	Final Selection
Feasibility, design and inclusion criteria of the study				
The brief requires us to design a complex intervention.	Agreed	1	92.9	As statement
Patients with non-injurious falls should be eligible for the intervention	Agreed	1	100.0	As statement
Fallers with an acute medical illness causing their fall, e.g. pneumonia or stroke, are included	No consensus	2	46.2	Include
Fallers should be recruited either within 1 week of the fall or 1 month of the fall	No consensus	2	53.8, 46.2	1 month
A feasible and useful sample size would be (% given for range of choices up to 30 participants)	No consensus	1	64.3	up to 30 participants
The number of sites included should be 3 sites.	Agreed	2	76.9	3 sites
It is feasible to recruit to WP4	Agreed	2	100.0	As statement
Setting of the study				
It would be useful to recruit participants presenting with a fall in the ED	Agreed	1	92.9	As statement
It would be useful to recruit participants presenting with a fall to paramedics if single ambulance stations are targeted	Agreed	1	92.9	As statement
It would be useful to recruit participants presenting with a fall in the primary care setting	Agreed	1	85.8	As statement
If we are recruiting participants who have had a fall within the last week, it would be useful for GPs to write to all patients on their QOF dementia register	No consensus	2	30.8	Rejected as we will not be recruiting patients up to one week after a fall
If we are recruiting participants who have had a fall within the last month, it would be useful for GPs to write to all patients on their QOF dementia register	Agreed	2	84.6	As statement
14. It would be useful to recruit participants in another setting.	Agreed	1	78.6	As statement

Statement	Outcome	Round	Percentage	Final Selection
Mean priorities for alternative settings				
Community services e.g. multidisciplinary outreach teams			3.1	Include
Domiciliary physiotherapy			4.6	Exclude
Supported discharge teams			3.4	Include
Telecare services			3.4	Include
Social services re-enablement teams			4.4	Exclude
Memory clinics			4.4	Exclude
Dementia cafes			5.5	Exclude
Social media			7.2	Exclude
The intervention should primarily take place in the patient's home	Agreed	1	85.7	As statement
The setting of the intervention should make use of existing pathways only when referral from the team deems it would be useful for the individual	Agreed	1	85.7	As statement
Content of the intervention (staff)				
A Physiotherapist should be routinely involved	Agreed	1	71.4	As statement
An Occupational therapist should be routinely involved	Agreed	1	71.4	As statement
A Geriatrician should be routinely involved via multidisciplinary team meeting and available for face to face consultation if required	No consensus	2	61.5	As statement
A Rehabilitation support worker should be routinely involved	Agreed	1	71.4	As statement
A Registered general nurse should be routinely involved via multidisciplinary team meeting and available for face to face consultation if required	No consensus	2	61.5	As statement
A Community psychiatric nurse should be available on referral	Agreed	1	71.4	As statement
A Social worker should be available on referral	Agreed	1	71.4	As statement
Re-enablement workers should be available on referral	Agreed	1	71.4	As statement
An Old Age Psychiatrist should be available on referral	Agreed	2	84.6	As statement
A Podiatrist should be available on referral	Agreed	2	92.3	As statement
Content of the intervention (assessment)				
Assessment should involve multiple sources of information including information from carers	Agreed	1	100.0	As statement
Assessment should include direct observation	Agreed	1	100.0	As statement

Statement	Outcome	Round	Percentage	Final Selection
Formal assessments of gait and balance should be carried out by the Timed Up and Go test	No consensus	2	61.5	As statement
A home hazard assessment should include a walk around the house to determine where actual falls have occurred and negotiate how these might be reduced	Agreed	1	92.9	As statement
An assessment of comorbidities is required	Agreed	1	100.0	As statement
An osteoporosis risk assessment is required	Agreed	1	92.9	As statement
A vision assessment is required	Agreed	1	100.0	As statement
A medication review is required	Agreed	1	100.0	As statement
All patients require attendance for a lying and standing BP	No consensus	2	53.8	As statement : to be carried out by therapist in the patient's home
A continence assessment is required	Agreed	1	78.6	As statement
An assessment of challenging behaviour is required	Agreed	1	92.9	As statement
Tools which assess non-verbal signs of pain should be used	Agreed	1	92.9	As statement
A multidisciplinary team meeting should be available if needed	Agreed	1	92.9	As statement
Carer stress should be routinely assessed	Agreed	1	92.9	As statement
Content of the intervention (methodology and quantity)				
Interventions should be based on goals set by the patient and carer	Agreed	1	85.7	As statement
Therapists should work with service users to minimise the risk of falling, as this may improve confidence and enable realistic risk taking.	Agreed	1	100.0	As statement
Therapists should facilitate caregivers, family and friends to adopt a positive approach to risk	Agreed	1	100.0	As statement
Exercise interventions should be informed by evidence based formats such as the Otago programme but tailored to the circumstances of PWD and embedded in their daily life	Agreed	2	69.2	As statement
The total number of physiotherapy sessions available in the first 3 months (including sessions delivered by a support worker) should be 16, 20 or 24	No consensus	2	30.8, 38.5, 30.8	20 sessions: Twice weekly (weeks 0-8)

Statement	Outcome	Round	Percentage	Final Selection
				tapering to once weekly (weeks 9-12)
The total number of occupational therapy sessions available in the first 3 months should be 3-4	No consensus	2	61.5	4
Therapists should offer service users information on assistive devices and facilitate delivery	Agreed	1	100.0	As statement
Therapists should help the service user and caregiver to develop a meaningful programme of activities	Agreed	1	100.0	As statement
Therapists should undertake observed activities with the service user to facilitate new learning	Agreed	1	92.9	As statement
Intervention staff should be able to provide basic carer education & support, referring to other agencies as needed	Agreed	2	76.9	As statement
Staff training				
Tier 2 training is required for intervention staff	Agreed	2	84.6	As statement
Training needs to include how to tailor an intervention for PWD	Agreed	1	100.0	As statement
Training needs to include advice on how to engage and motivate PWD	Agreed	1	100.0	As statement
Training should include on the job role modelling	Agreed	1	100.0	As statement
Outcome measures for the intervention				
The primary outcome measure be a numerical measure of falls	Agreed	2	76.9	As statement
Secondary outcomes should include health related quality of life measure	Agreed	1	100.0	As statement
The best health related quality of life measure would be Quality of life in Alzheimer's disease (QOL-AD)	Agreed	2	69.2	As statement
Secondary outcomes should include activities of daily living measure	Agreed	1	92.9	As statement
The best activities of daily living measure would be Disability Assessment for Dementia (DAD)	Agreed	2	84.6	As statement
Secondary outcomes should include carer burden measure	Agreed	1	92.9	As statement
The best carer burden measure would be Zarit Burden interview	Agreed	2	69.2	As statement
Secondary outcomes should include psychological consequences of falling measure	Agreed	1	85.7	As statement

Statement	Outcome	Round	Percentage	Final Selection
The best psychological consequence measure e.g. fear of falling would be the Modified Falls Efficacy scale	Agreed	1	71.4	As statement
Secondary outcomes should include physical activity measure	No consensus	1	64.2	As statement
The best physical activity measure would be a wearable physical activity monitor	Agreed	1	78.6	As statement
Secondary outcomes should include Strength and balance measure	No consensus	1	57.1	As statement- this would be TUG as in initial assessement
Secondary outcomes should include goal setting or performance measure	No consensus	1	35.7	As statement
The best goal setting or performance measure would be Goal Attainment scaling	Agreed	2	84.6	As statement
The best carer quality of life measure would be EQ-5D- 5L	No consensus	1	57.1	Exclude- see below
The most popular Carer quality of life measure was EQ-5D-5L, but it was suggested that a measure of carer burden would be sufficient.	No consensus	2	53.8	As statement
Prioritise the remaining domains where consensus was not achieved (1 highest - 4 lowest)				
Goal setting measure		2	2.0	include
Physical activity measure		2	2.5	include
Strength and balance measure		2	2.5	include
Carer quality of life		2	3.0	exclude

15.2 Appendix 2 READ codes for diagnosis of dementia

The appropriate Read codes for adding a person to a GP dementia QOF register have been described by Russell et al [20]and are available at: http://bmjopen.bmj.com/content/suppl/2013/12/20/bmjopen-2013-004023.DC1.html

Where some diagnostic data are available the codes **Eu00.** can be used for Alzheimer's disease, **Eu002** for mixed dementia, and **Eu01.** for vascular dementia. All others can be given **Eu02z.**

Recommended READ codes

ICD	Diagnosis	READ
F00	Dementia in Alzheimer's disease	**Eu00.**
F00.2	Dementia in Alzheimer's disease, atypical or mixed type ("Mixed Dementia")	**Eu002**
F01	Vascular dementia	**Eu01.**
F03	Unspecified dementia	**Eu02z**

Where detailed information on subtype of dementia is available, then the READ codes below can be used. This matches ICD10 codes to recognised general practice dementia READ codes.

All READ codes

ICD10	Diagnosis	READ
F00	Dementia in Alzheimer's disease	Eu00.
F00.0	Dementia in Alzheimer's disease with early onset	Eu000
F00.1	Dementia in Alzheimer's disease with late onset	Eu001
F00.2	Dementia in Alzheimer's disease, atypical or mixed type	Eu002
F00.9	Dementia in Alzheimer's disease, unspecified	Eu00z
F01	Vascular dementia Arteriosceloritic dementia	Eu01. E004
F01.1	Multi-infarct dementia	Eu011
F01.2	Subcortical vascular dementia	Eu012
F01.3	Mixed cortical and subcortical vascular dementia	Eu013
F01.8	Other vascular dementia	Eu01y
F01.9	Vascular dementia, unspecified Uncomplicated arteriosclerotic dementia Arteriosclerotic dementia with delirium Arteriosclerotic dementia with paranoia Arteriosclerotic dementia with depression Arteriosclerotic dementia NOS	Eu01z E0040 E0041 E0042 E0043 E004z
F02	Dementia in other diseases classified elsewhere	Eu02.
F02.0	Dementia in Pick's disease	Eu020
F02.1	Dementia in Creutzfeldt-Jakob disease	Eu021
F02.2	Dementia in Huntingdon's disease	Eu022

F02.3	Dementia in Parkinson's disease	Eu023
F02.4	Dementia in HIV disease	Eu024
F02.8	Dementia in other disease classified elsewhere Dementia in conditions	Eu02y E041
F03	Unspecified dementia	Eu02z
	Presenile dementia	E001.
	Uncomplicated presenile dementia	E0010
	Presenile dementia with delirium	E0011
	Presenile dementia with paranoia	E0012
	Presenile dementia with depression	E0013
	Presenile dementia NOS	E001z
	Uncomplicated senile dementia	E000
	Senile dementia with depressive or paranoid features	E002
	Senile dementia with paranoia	E0020
	Senile dementia with depression	E0021
	Senile dementia with depressive or paranoid features NOS	E002z
F05.1	Delirium superimposed on dementia	Eu041
	Senile dementia with delirium	E003
F05.9	Delirium, unspecified	Eu04z
F06.0	Organic hallucinosis	Eu050
	Other senile and presenile organic psychoses	E00y
	Senile or presenile psychoses	E00z
F06.7	Mild cognitive disorder	Eu057
F10.7	Residual and late onset psychotic disorder due to alcohol.	Eu107
	Including:	Eu10711
	- Alcoholic dementia	E012
	- Other alcoholic dementia	E0120
	- Chronic alcoholic brain syndrome	
G30	Alzheimer's disease	F110.
G30.8	Other Alzheimer's disease	
G30.9	Alzheimer's disease, unspecified	
G30.0	Alzheimer's disease with early onset	F1100
G30.1	Alzheimer's disease with late onset	F1101
G31.0	Circumscribed brain atrophy. Including;	
	- Fronto-temporal dementia	No Code
	- Pick's disease	F111.
	- Progressive isolated aphasia	
G31.1	Senile degeneration of the brain, not elsewhere classified	F112.
G31.8	Other specified degenerative disease of the nervous system.	
	Including:	
	- Grey matter degeneration	
	- Lewy body disease	F116
	- Lewy body dementia	Eu025
	- Subacute necrotizing encephalopathy	

15.3 Appendix 3 – Amendment History

Amendment Number	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
1	Version 2.0	12th October 2017	Louise Allan	Changes made to version 1.0 in response to provisional opinion of ethics committee. Use of physical activity monitors removed from protocol.

(Enter all amendments to the protocol here whether substantial or non-substantial. Substantial amendments will require approval by the REC. Non-substantial amendments should be sent to the REC for acknowledgement only}

15.4 Appendix 4 Topic guides for qualitative interviews and focus groups

We have produced a series of overlapping topic guides for different stakeholders. This will enable us to explore a range of perspectives on the DIFRID intervention and to identify ways of optimising the intervention prior to a full trial. The different stakeholder groups to be interviewed are:

- PWD and informal carers receiving the intervention (up to 15 dyads)
- Staff responsible for recruitment & collection of outcome data (up to 6)
- Staff responsible for developing the intervention, training and supervising intervention delivery and delivering the intervention (up to 10)
- Members of the multidisciplinary team (up to 6)
- Health and social care professionals involved in the care of patients receiving the intervention (Up to 6)

Staff responsible for recruitment and assessment of outcomes

Introduction (Introduce self & explain aspects of interview process)

- Please don't feel the need to be polite or restrained; we need your honest feedback and suggestions. Reassure re confidentiality.

Can you start by telling me about how the recruitment process has worked in practice?

- What has been successful?
- What have the main challenges been?

How interested do patients seem to be in the intervention?

- What strategies have you used when explaining the study to patients and trying to engage them?
- From your perspective, what are the facilitators and barriers to getting people/patients engaged in the study?
- What else could we do to make the intervention more appealing to patients and informal carers?

Have there been any patients who met the inclusion criteria but you felt were not appropriate for the study?

- Would you suggest any changes to the inclusion/exclusion criteria?

What sense do you have of how feasible it would be to proceed to a full trial with a control group etc?

- Are there any changes you would recommend to recruitment processes?
- Was there any additional support you needed to recruit patients?
- Was there anything in the recruitment materials (PIS, consent forms) that could be improved?

Can you tell me about how the assessment processes and outcome measures have worked in practice?

- From your contact with patients and informal carers, to what extent do you feel the outcome measures are capturing the difference that the intervention has made to their lives?

What sense do you have of how useful the intervention is?

When we were designing the intervention, we developed some theories about how we thought it would work. (describe theories from realist review) Does this line up with your experience?

Staff responsible for developing the intervention and training and supervising intervention delivery

How do you think the training went?

- What worked well?
- What might you do differently in the future?
- In terms of taking this work forward, how could we improve the initial training session(s)?

How has the supervision process been?

- How frequently have you met?
- What have been the main issues raised in supervision?
- Is there anything that could be improved?

How do you think the study/intervention is going so far?

How confident are you in the intervention?

What reservations do you have about the intervention?

Which aspects of the DIFRID intervention do you feel most confident with/have been most useful?

Which aspects of the DIFRID intervention do you find most challenging/have been least useful?

Overall, what sense do you have of how useful the intervention is?

In this study, the DIFRID intervention is delivered by physiotherapists, occupational therapists and rehabilitation assistants. From your perspective what are the advantages and disadvantages of using staff with this skill mix?

What kinds of patients do you think would benefit most from this type of intervention? Are there patients for whom it would not be useful?

How interested do patients seem to be in the intervention?

From your perspective, what are the facilitators and barriers to getting people/patients engaged in the study?

From your perspective, what are the facilitators and barriers to implementing the intervention?

From your perspective, what are the facilitators and barriers to evaluating the acceptability and impacts of the DIFRID intervention?

Are there any changes we should make to the DIFRID intervention?

Is there anything else that we haven't covered about the DIFRID intervention?

When we were designing the intervention, we developed some theories about how we thought it would work. (describe theories from realist review) Does this line up with your experience?

Staff delivering the intervention

What are/were your expectations about the DIFRID intervention?

How do you think the study/intervention is going so far?

How confident are you in the intervention?

What reservations do you have about the intervention?

Which aspects of the DIFRID intervention do you feel most confident with/have been most useful?

Which aspects of the DIFRID intervention do you find most challenging/have been least useful?

What opportunities have you had to discuss the value of the intervention with your colleagues?

How might we modify the DIFRID intervention?

From your perspective, what are the facilitators and barriers to implementing the intervention?

Overall, what sense do you have of how useful the intervention is?

In this study, the DIFRID intervention is delivered by physiotherapists, occupational therapists and rehabilitation assistants. From your perspective what are the advantages and disadvantages of using staff with this skill mix?

What kinds of patients do you think would benefit most from this type of intervention? Are there patients for whom it would not be useful?

Based on feedback from supervision, how interested do patients seem to be in the intervention?

From your perspective, what are the facilitators and barriers to getting people/patients engaged in the study?

Could you describe the process of tailoring the intervention to the individual patient?

- How well did you think this worked in practice?
- What were the facilitators and barriers to tailoring and embedding?

How helpful were different components of the intervention (e.g. training, manual, MDT meetings, supervision)?

Are there any changes we should make to the intervention materials (e.g. the assessment form)?

From your perspective, how well did the intervention 'fit' with other services?

Do you feel you have the support you need to deliver the intervention?

How do you think the training went?

- What worked well?
- What do you think could have been done differently?

How well has the supervision process gone?

- Is there anything that could be improved?
- Was there any training or support that you felt you needed but didn't receive?

In terms of taking this work forward, how could we improve the initial training session(s)?

How will your experience with the DIFRID intervention influence your usual practice in the future?

Is there anything else that we haven't covered about the DIFRID intervention?

When we were designing the intervention, we developed some theories about how we thought it would work. (describe theories from realist review) Does this line up with your experience?

Members of the multidisciplinary team

What are/were your expectations about the DIFRID intervention?

How do you think the intervention is going so far?

How confident are you in the intervention?

What reservations do you have about the intervention?

Which aspects of the DIFRID intervention do you feel most confident with/have been most useful?

Which aspects of the DIFRID intervention do you find most challenging/have been least useful?

From your perspective, what are the facilitators and barriers to implementing the intervention?

Overall, what sense do you have of how useful the intervention is?

If we were taking the intervention forward, how might you change it?

In this study, the DIFRID intervention is delivered by physiotherapists, occupational therapists and rehabilitation assistants. From your perspective what are the advantages and disadvantages of using staff with this skill mix?

What kinds of patients do you think would benefit most from this type of intervention? Are there patients for whom it would not be useful?

From your perspective, what are the facilitators and barriers to getting people/patients engaged in the study?

What have been the benefits of including an MDT in the intervention?

- For patients/informal carers?
- For staff delivering the intervention?
- For yourself?

How well did the MDT meetings work in practice/logistically?

Are there any changes we should make to the MDT process?

Is there anything else that we haven't covered about the DIFRID intervention?

Health and social care professionals involved in the care of patients receiving the intervention

(Professionals to whom referrals have been made as part of the DIFRID intervention, or who were delivering services to the patient or informal carer during the intervention period)

We are interested in how the DIFRID intervention fits with other existing services.

Can you tell me about your involvement with <*name*>?

Did you have any contact with staff delivering the DIFRID intervention?

- Can you tell me a bit more about that?

Did the fact that <*name*> was also receiving the DIFRID intervention impact on your work at all?

- Time constraints
- Overlap/conflicting advice

In this study, the DIFRID intervention is delivered by physiotherapists, occupational therapists and rehabilitation assistants. From your perspective what are the advantages and disadvantages of using staff with this skill mix?

From your perspective, what are the facilitators and barriers to implementing the intervention?

Have you been involved in helping <*name*> with any activities related to the intervention?

- IF YES: Can you tell me a bit more about that? (time taken, whether appropriate, confidence in ability to assist, training needs, fit with usual activities with <*name*>)

Overall, what sense do you have of how useful the intervention is?

How might we modify the DIFRID intervention?

Is there anything else that we haven't covered about the DIFRID intervention?

When we were designing the intervention, we developed some theories about how we thought it would work. (describe theories from realist review) Does this line up with your experience?

Patients receiving the intervention

Did you feel this was a good intervention for you?

- Tell me more about that

What did you like about the intervention sessions?

What did you dislike? What could have been different?

Which aspects of the DIFRID intervention have been most useful?

Which aspects of the DIFRID intervention have been least useful?

How did you feel about the activities that you were asked to do? (Were they personalised enough?)

Has the intervention made any difference to you?

- Mobility
- Confidence
- Activities
- Number of falls
- Anything else?
- Are there any areas you were hoping the intervention would improve that haven't improved?

Thinking about the intervention materials such as the diary and the manual, are there any changes that you think we should make?

Could you tell me a bit about the staff delivering the intervention?

- Were they knowledgeable?
- How well did you think they communicated and interacted with you?

Can you tell me a bit about the goal you have been working towards?

- How did you chose that as a goal?
- How much progress have you made?
- How did you feel about the process of setting goals?
- Do you feel you have as much help as you need to help you achieve your goals?
- What else would help?

What kinds of patients do you think would benefit most from this type of intervention? Are there patients for whom it would not be useful?

Is there anything else that we haven't covered about the DIFRID intervention?

Informal carers of patients receiving the intervention

What were/are your expectations about the DIFRID intervention?

Did you feel this was a good intervention for <*name*>?

- Tell me more about that
- What did you like about the intervention sessions?
- What did you dislike? What could have been different?
- How engaged did <*name*> seem to be in the intervention?
- Which aspects of the DIFRID intervention have been most useful?
- Which aspects of the DIFRID intervention have been least useful?
- How did you feel about the goals that <*name*> has been working towards?

Has the intervention made any difference to <*name*>?

- Mobility
- Confidence
- Activities
- Number of falls
- Anything else?
- Are there any areas you were hoping the intervention would improve that haven't improved?

What about yourself, how involved have you been in the intervention?

- Were you satisfied with that level of involvement?
- Did you receive any education or training? Was it useful?
- Has the intervention had any impacts on you?
- Is there anything we could have done differently to help you?

Thinking about the intervention materials such as the diary and the manual, are there any changes that you think we should make?

The DIFRID intervention is delivered by physiotherapists, occupational therapists and rehabilitation assistants. From your perspective what are the advantages and disadvantages of using staff with this skill mix?

Could you talk about your perception of the staff delivering the intervention?

- Were they knowledgeable?
- How well did you think they communicated and interacted with you?

What kinds of patients do you think would benefit most from this type of intervention? Are there patients for whom it would not be useful?

Is there anything else that we haven't covered about the DIFRID intervention?